UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

11 CIV 0233

SHIRE CANADA INC., SHIRE INTERNATIONAL LICENSING B.V., AND SHIRE US INC.,

Plaintiffs,

- v -

ALKEM LABORATORIES, LTD.,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Civ. Action No.

ECF CASE

Plaintiffs Shire Canada Inc., Shire International Licensing B.V., and Shire US Inc. (collectively, "Shire"), by their attorneys, for their complaint against Alkem Laboratories, LTD. ("Alkem"), allege as follows:

The Parties

1. Plaintiff Shire Canada Inc. is a corporation organized and existing under the laws of Canada and has a principal place of business at 2250, boul. Alfred-Nobel, bureau 500, Ville St-Laurent, QC H4S 2C9, Canada.

2. Plaintiff Shire International Licensing B.V. is a corporation organized and existing under the laws of the Netherlands and has a principal place of business at Strawinskylaan 847, 1077 XX Amsterdam, Noord-Holland, The Netherlands.

3. Plaintiff Shire US Inc. is a corporation organized and existing under the laws of New Jersey and has a principal place of business at 725 Chesterbrook Blvd., Wayne, PA 19087, United States.

4. Upon information and belief, Defendant Alkem is a corporation organized and existing under the laws of India and has a principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (W), Mumbai, India - 400013.

Jurisdiction and Venue

5. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent Nos. 5,968,976 ("the '976 patent") and 7,465,465 ("the '465 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Alkem is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, having availed itself of the rights and benefits of New York law, and having engaged in substantial and continuing contacts with the State and with the United States, including, but limited to, purposefully directing product sales and marketing efforts toward New York and the United States.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for Approval of New and Generic Drugs

8. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by the Food and Drug Administration ("FDA") – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to

FDA extensive animal and human clinical trial data at a substantial cost of time and money.

9. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an Abbreviated New Drug Application ("ANDA") for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

10. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

11. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

12. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

13. Shire is the holder of an approved new drug application, NDA No. 21-468, for lanthanum carbonate chewable tablets. That NDA was approved for tablets of Eq. 500 mg base on October 26, 2004, and for tablets of Eq. 750 mg base and Eq. 1000 mg base on November 23, 2005.

14. Pursuant to FDA's approval, Shire currently markets lanthanum carbonate chewable tablets for reduction of serum phosphate in patients with end stage renal disease under the trademark FOSRENOL®.

15. FDA has listed the '976 patent and the '465 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-468.

16. The '976 patent and the '465 patent qualify for listing in the Orange Book in connection with NDA No. 21-468 because they claim an approved use of the drug product that is the subject of that NDA. Alkem has never challenged the listing of these patents in the Orange Book.

Alkem's ANDA

17. Alkem has represented that on or before December 1, 2010, it submitted to FDA an ANDA (ANDA No. 202,329) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21

U.S.C. § 355(j)(2)(A)(vii)(IV), for lanthanum carbonate chewable tablets purportedly bioequivalent to Shire's FOSRENOL® lanthanum carbonate chewable tablets. The purpose of Alkem's ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed lanthanum carbonate chewable tablets before the expiration of the patents listed in the Orange Book for Shire's NDA No. 21-468. Hence, Alkem's purpose in submitting ANDA No. 202,329 is to market in the United States the lanthanum carbonate products described therein before expiration of the '976 patent and the '465 patent.

18. On or about December 1, 2010, Alkem sent a letter advising Shire of Alkem's paragraph IV certification relating to the '976 patent and the '465 patent ("Alkem's Notice Letter"). Alkem's Notice Letter included an offer of confidential access that would permit Shire's outside counsel to review Alkem's ANDA, subject to conditions limiting its distribution and use. Alkem's Notice letter is attached hereto as Exhibit A.

19. Upon information and belief, the sole condition of use for which Alkem seeks approval in its ANDA No. 202,329 for its proposed lanthanum carbonate chewable tablets is the reduction of serum phosphate in patients with end stage renal disease, the same condition of use as that approved in Shire's NDA No. 21-468.

20. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Alkem in its ANDA No. 202,329 for its proposed lanthanum carbonate chewable tablets is the reduction of serum phosphate in patients with end stage renal disease, the same indication as that set forth in the approved labeling for Shire's FOSRENOL® lanthanum carbonate chewable tablet products.

Count 1: Patent Infringement – '976 patent

21. Shire realleges paragraphs 1 through 20 above as if fully set forth herein.

22. On October 19, 1999, the United States Patent and Trademark Office duly and legally issued the '976 patent, entitled "Pharmaceutical Composition Containing Selected Lanthanum Carbonate Hydrates." The term of the '976 patent runs through October 26, 2018. A true and correct copy of the '976 patent is attached hereto as Exhibit B.

23. Shire is the owner of the '976 patent.

24. Shire currently markets lanthanum carbonate chewable tablets in the United States under the trademark FOSRENOL®. The product FOSRENOL® and the conditions of use for which FOSRENOL® is approved fall within one or more of the claims of the '976 patent.

25. Alkem is liable for infringement of the '976 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 202,329 with a paragraph IV certification seeking FDA approval of ANDA No. 202,329 prior to expiration of the '976 patent.

26. The product for which Alkem seeks approval in its ANDA No. 202,329 falls within one or more of the claims of the '976 patent. If approved, the manufacture, use, offer for sale, and sale in the United States, and importation into the United States of Alkem's proposed lanthanum carbonate product would infringe one or more of the claims of the '976 patent.

27. Upon information and belief, if ANDA No. 202,329 is approved, Alkem intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the lanthanum carbonate product for which approval is sought in Alkem's ANDA No. 202,329.

28. The manufacture, use, offer for sale and sale in the United States, and importation into the United States of Alkem's proposed lanthanum carbonate product would infringe one or more claims of the '976 patent, and Alkem would be liable for direct infringement under 35 U.S.C. § 271(a).

29. Alkem's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '976 patent, of the lanthanum carbonate products for which approval is sought in ANDA No. 202,329, would actively induce and contribute to infringement of the '976 patent, and Alkem would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

30. Upon information and belief, the conditions of use for which Alkem seeks approval in its ANDA No. 202,329 fall within one or more of the claims of the '976 patent. Upon information and belief, if approved, use of Alkem's proposed lanthanum carbonate product in accordance with the proposed labeling submitted in ANDA No. 202,329 would infringe one or more of the claims of the '976 patent.

31. Upon information and belief, if approved, Alkem's proposed lanthanum carbonate products for which approval is sought in Alkem's ANDA No. 202,329 will be administered to human patients in a therapeutically effective amount for reduction of serum phosphate in patients with end stage renal disease, which administration would constitute direct infringement of one or more claims of the '976

patent. Upon information and belief, this infringement will occur at Alkem's behest, with its intent, knowledge, and encouragement, and Alkem will actively induce, encourage, aid, and abet this administration that is in contravention of Shire's rights under the '976 patent.

32. Shire will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing or contributing to infringement of the '976 patent. Shire does not have an adequate remedy at law.

Count 2: Patent Infringement – '465 patent

33. Shire realleges paragraphs 1 through 20 above as if fully set forth herein.

34. On December 16, 2008, the United States Patent and Trademark Office duly and legally issued the '465 patent, entitled "Pharmaceutical Formulation Comprising Lanthanum Compounds." The term of the '465 patent runs through August 26, 2024. The applicant has petitioned the PTO to extend the term of the patent by 44 days, through October 9, 2024. A true and correct copy of the '465 patent is attached hereto as Exhibit C.

35. Shire is the owner of the '465 patent.

36. Shire currently markets lanthanum carbonate chewable tablets in the United States under the trademark FOSRENOL®. The product FOSRENOL® and the conditions of use for which FOSRENOL® is approved fall within one or more of the claims of the '465 patent.

37. Alkem is liable for infringement of the '465 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 202,329 with a paragraph IV certification seeking FDA approval of ANDA No. 202,329 prior to expiration of the '465 patent.

38. The product for which Alkem seeks approval in its ANDA No. 202,329 falls within one or more of the claims of the '465 patent. If approved, the manufacture, use, offer for sale, and sale in the United States, and importation into the United States of Alkem's proposed lanthanum carbonate product would infringe one or more of the claims of the '465 patent.

39. Upon information and belief, if ANDA No. 202,329 is approved, Alkem intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the lanthanum carbonate product for which approval is sought in Alkem's ANDA No. 202,329.

40. The manufacture, use, offer for sale and sale in the United States, and importation into the United States of Alkem's proposed lanthanum carbonate product would infringe one or more claims of the '465 patent, and Alkem would be liable for direct infringement under 35 U.S.C. § 271(a).

41. Alkem's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '465 patent, of the lanthanum carbonate products for which approval is sought in ANDA No. 202,329, would actively induce and contribute to infringement of the '465 patent, and Alkem would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

42. Upon information and belief, the conditions of use for which Alkem seeks approval in its ANDA No. 202,329 fall within one or more of the claims of the '465 patent. Upon information and belief, if approved, use of Alkem's proposed lanthanum carbonate product in accordance with the proposed labeling submitted in ANDA No. 202,329 would infringe one or more of the claims of the '465 patent.

43. Upon information and belief, if approved, Alkem's proposed lanthanum carbonate products for which approval is sought in Alkem's ANDA No. 202,329 will be administered to human patients in a therapeutically effective amount for reduction of serum phosphate in patients with end stage renal disease, which administration would constitute direct infringement of one or more claims of the '465 patent. Upon information and belief, this infringement will occur at Alkem's behest, with its intent, knowledge, and encouragement, and Alkem will actively induce, encourage, aid, and abet this administration that is in contravention of Shire's rights under the '465 patent.

44. Shire will be irreparably harmed if Alkem is not enjoined from infringing or actively inducing or contributing to infringement of the '465 patent. Shire does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Alkem has infringed the '976 patent and the '465 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of the Alkem ANDA No. 202,329 for

lanthanum carbonate chewable tablets be not earlier than the later of the expiration dates of the '976 patent and the '465 patent;

C. A judgment declaring that Alkem's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the lanthanum carbonate products for which approval is sought in ANDA No. 202,329 would constitute infringement of the '976 patent and the '465 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Alkem and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the lanthanum carbonate chewable tablets for which approval is sought in ANDA No. 202,329, or any lanthanum carbonate product that infringes or induces or contributes to the infringement of the '976 patent or the '465 patent, until after expiration of those patents;

E. A finding that Alkem's paragraph IV certification is frivolous, a finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

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